Advancing Research Solutions to Chronic Lung Allograft Dysfunction

Request for Research Grant Applications

POLICIES AND GUIDELINES

Published: May 31, 2018
Letter of Intent Deadline: July 10, 2018
Full Application Deadline: September 24, 2018

PLEASE NOTE: FULL APPLICATIONS WILL ONLY BE ACCEPTED FROM APPLICANTS WITH AN APPROVED LETTER OF INTENT (LOI)
I. ABOUT THE CYSTIC FIBROSIS FOUNDATION
The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. To meet this mission, various types of awards are offered to support meritorious research ranging from basic laboratory investigation to clinical management of CF.

II. BACKGROUND
Cystic fibrosis is a common, lethal autosomal recessive disorder that affects approximately 70,000 individuals worldwide. Abnormal mucus production in the respiratory tract is the primary cause of morbidity and mortality in CF, but other organs are also affected including the pancreas, sweat gland, intestine, bile duct of the liver, and male reproductive system. CF is caused by dysfunction of a single gene, Cystic Fibrosis Transmembrane Conductance Regulator (CFTR), which codes for a chloride (Cl-) channel at the apical membrane of epithelial cells. Close to 2,000 variants of CFTR have been identified. Clinical development of small molecule CFTR modulators that reverse the folding defect holds promise for new therapies for the majority of people with CF. However, there is still an unmet need to improve the quality of life and life expectancy of patients with end-stage CF lung disease.

Lung transplantation is a treatment option for people with CF and advanced obstructive lung disease resulting from lung infection, inflammation, and progressive bronchiectasis. While the transplant surgery replaces the damaged lung, people with CF are susceptible to post-transplant lung infections due to complications of immune suppression, graft rejection, and chronic lung allograft dysfunction (CLAD) which impact long-term survival. Approximately 200 to 250 people with CF in the United States receive lung transplants each year, however, post-transplant survival is suboptimal. To address these issues, it will be necessary to better understand transplant biology and the mechanisms of actions for lung rejection.

The Cystic Fibrosis Foundation has started a CF lung transplant initiative to address the unmet needs of people with CF and advanced lung disease. The mission of this initiative is to improve the care and long-term outcomes of individuals with CF and advanced lung disease by optimizing medical therapies, decision-making and access to lung transplantation and improving outcomes after lung transplantation. Towards this end, the CF Foundation is supporting research for strategies for early detection and intervention of CLAD following lung transplantation.

III. RESEARCH OBJECTIVES AND AWARD OVERVIEW
Cystic Fibrosis Foundation announces a Request for Applications (RFA) to identify and support highly meritorious research proposals in lung transplantation that will improve the understanding of the mechanisms involved in CLAD and identify paths toward the development of therapies that might either prevent or treat CLAD.

The objective of this RFA is to fund highly meritorious research projects that will aid in understanding the mechanism(s) of lung transplant rejection and identifying approaches to improve survival in cystic fibrosis patients post lung transplantation. Projects of interest include areas addressing: (1) transplant immunology and, (2) advancing technology platforms and animal models to support studies of lung infections and acute and chronic allograft dysfunction, particularly bronchiolitis obliterans syndrome.
Areas of interest include, but are not limited to:
• Endotyping of CLAD
• The understanding of CLAD pathogenesis towards ultimately identifying new therapeutic targets
• The development of technologies, testing modalities, and model systems for diagnosing CLAD early and monitoring CLAD progression
• The role of the microbiome and CF pathogens in the development of CLAD
• Transplant immunology including immunophenotyping, understanding cellular and humoral immune changes corresponding to lung infections after lung transplantation, and exploring therapeutic uses of immune cells

A goal of this RFA is to promote collaboration between investigators with complementary expertise and/or shared knowledge and common resources. Larger funded research awards are available for collaborative proposals, which are encouraged.

General Guidelines and Eligibility:
• Collaborative research awards will be considered for funding up to $350,000 per year for up to two (2) years, plus eight percent (8%) indirect costs to support integrated, multiple independent investigator projects collaborating around a common theme or topic.
• One application is required for collaborative projects. A PI must submit one application on behalf of all participating PIs, and the budget must include a lead site with the other participating sites as subcontractors.
• Collaborative research awards may be considered for renewal for a third year of funding after the initial funding cycle based on progress toward achieving the aims of the project and the availability of funds.
• Funding for independent smaller research awards up to $150,000 per year for up to two (2) years, plus eight percent (8%) indirect costs will be considered.
• United States residents and applicants from outside the United States are welcome to apply.

IV. REVIEW AND AWARD
Applications will be reviewed by a CFF ad hoc review committee. Awards are based upon the availability of funds, the merit of the application, and the recommendations of the reviewers. All awards will be made in compliance with the regulations and CFF policies.

Proposals should clearly demonstrate how the research will advance our understanding of transplant biology and outcomes of lung transplant for individuals with cystic fibrosis as it specifically relates to CLAD.

Applications will be evaluated on the following:
• Relevance to the priority areas stated above
• Scientific merit of the project as described in the applicant’s Research Plan
• PI’s background and experience
• Adequate facilities and research environment for the project
• Collaborative projects
  o How the individual applicant fits within the larger collaboration?
  o Synergy among the groups
Low priority scores in the reviews commonly result from the following shortcomings of the application:

- Failure to address the evaluation criteria described above
- Insufficient information or documentation
- Inadequate statement of hypotheses, experimental design or methods
- Failure to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the proposed research
- Insufficient or improper controls
- Failure to describe potential relevance of the proposed study to issues in lung transplantation for CF
- Failure to document the necessary skills or training to accomplish the goals of the proposal
- Failure to identify access to resources outlined in the application (e.g., airway epithelial cells)
- For collaborative projects, insufficient justification for collaboration or inadequate description of how the collaboration will be executed.

V. SUBMISSION INFORMATION AND GENERAL TIMELINE

A Letter of Intent (LOI) must be submitted and approved prior to submitting a Full Application.

Submit online at proposalCENTRAL: https://proposalcentral.altum.com/
(Refer to Section VII and Section VI of these guidelines for specific submission instructions)

General Timeline

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<td>July 10, 2018</td>
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<td>LOI Applicant Notified</td>
<td>mid-August 2018</td>
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<td>Full Application Deadline</td>
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<tr>
<td>Review Committee Meeting</td>
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<td>Applicant Notified</td>
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<td>Award Letter Issued</td>
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VI. LETTER OF INTENT (LOI) SUBMISSION GUIDELINES

LOI Submission Deadline: Tuesday, July 10, 2018 at 5:00 PM (EST)

LOIs must be submitted online at proposalCENTRAL: https://proposalcentral.altum.com/

An LOI will be considered incomplete if it fails to comply with these instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews LOIs electronically, and only documents submitted online at proposalCENTRAL will be reviewed.
Documents should be typed using:
• Font: Times New Roman 12 or Arial 11.
• Margins: No less than a half inch on each side.

Log-in at proposalCENTRAL: https://proposalcentral.altum.com/. You must create an account and a profile before applying. If you have registered and cannot remember your password, click on the “Forgot Your Username/Password?” link below the “Application Login” fields. Note: Use the Customer Service link on the top right of each screen as needed.

Select the gray tab labeled “Grant Opportunities” found in the upper right-hand side of the page.

Click on the light blue “Filter by Grant Maker” button to the left and scroll down to locate Cystic Fibrosis Foundation in the list.

Locate the listing for the “Advancing Research Solutions to Chronic Lung Allograft Dysfunction” program. Click on the “Apply Now” button in the column on the far right to open the application.

Applicants may stop at any point but must click the “Save” button before exiting in order to save their work. When logging in to continue, click on the blue tab, “Manage Proposals”, and then the “Edit” button.

The following sections are listed in the navigation menu to the left of the application screen.

1. Title Page: Enter the title of your project.

2. Download Templates & Instructions: Download the available template(s), complete and upload as PDF documents in Section #6. Templates available include: LOI Cover Sheet, LOI Project Description, and Biographical Sketch(es) of Key Personnel.

3. Enable Other User to Access this Proposal: Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Click on “Accept Changes”.

4. Applicant/PI: If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the information in the required fields and click “Save”.

5. Institution: If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “Save”. Be sure to use the full legal name of the institution.
6. **Budget Summary:** Fill in the start date and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2). All Lung Transplantation Awards are awarded for a maximum of two (2) years, up to:
- $350,000 per year in direct costs (plus 8% indirect costs) for a Collaborative Project
- $150,000 per year in direct costs (plus 8% indirect costs) for an Independent Project

7. **Attachments:** Complete the template(s) downloaded from Section #2 and upload them here as PDF documents. Below are instructions specific to each template.
   A. **Letter of Intent Cover Sheet (template available for download)**
      The Principal Investigator is required to sign where indicated. (The Awardee Institution’s Authorized Institutional Official’s signature is not required for the LOI). Scan and upload.
   B. **Letter of Intent Project Description (template available for download)**
      Upload a PDF copy of the completed document. Maximum of three (3) pages (not including the literature cited). Components should include:
      a. **Statement of Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation.
      b. **Brief Study Design:** Describe the study design, including a statistical section. The statistical section must include a detailed power or a sample size analysis on the primary and major secondary analysis. These analyses should include formulas and estimates used to arrive at the sample.
      c. **Literature Cited:** References should be numbered in the sequence that they appear in the text. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).
   C. **Biographical Sketch(es) of Key Personnel (NIH template and example available for download)**
      CFF defines “key personnel” as any individual with an advanced degree who will play an instrumental role in the research project. An NIH Biographical Sketch form should be completed for each key personnel and uploaded as PDF. The maximum length for each biosketch is five (5) pages. Personnel must include a biostatistician with at least 5% effort on the project.

8. **Validate:** Upon completing your LOI, click on the “Validate” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “Validate” again.

9. **Signature Page(s):** Signature Page(s) are not required at the LOI stage. Continue to Section #10.

10. **Submit:** Click on the gray button with blue lettering Submit. CFF will not receive your application unless the submit button is clicked.

   **Confirmation:** Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the Letter of Intent was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contract proposalCENTRAL immediately to ensure the application was submitted and processed.
VII. FULL APPLICATION SUBMISSION GUIDELINES

A Letter of Intent (LOI) must be submitted and approved prior to submitting a full application.

Full Application Deadline: Monday, September 24, 2018 at 5:00 PM (EST)

Application must be submitted online at proposalCENTRAL: https://proposalcentral.altum.com/

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at proposalCENTRAL will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11.
- Margins: No less than a half inch on each side.

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section VII. ELECTRONIC APPLICATION CHECKLIST.

Log-in at proposalCENTRAL: https://proposalcentral.altum.com/

Applicants may stop at any point but must click the “Save” button before exiting in order to save their work. When logging in to continue, click on the blue tab, “Manage Proposals,” and then the “Edit” button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions.

1. **Title Page:** Enter the title of your project and indicate whether this is a resubmission of an application that was reviewed earlier (if applicable).

2. **Download Templates and Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #10. Templates available include: Results of Past and Current CFF/CFIT support, Budget Detail(s), Budget Justification(s), Facilities Available, Biographical Sketch(es), Other Support, Research Plan, Collaborative Project Description, Letters of Support instructions, Appendices, and International Institution Form (if applicable).

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “Permissions” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “Administrator” rights can submit applications on behalf of the applicant. Check the “Auto Notify” box and then “Save”.

Advancing Research Solutions to Chronic Lung Allograft Dysfunction
June 2018
4. **Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “Edit Professional Profile” button and follow the instructions. If a profile was not completed, enter the required information and click “Save”.

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “Save”. Be sure to use the full legal name of the institution.

6. **Abstracts/Relevance:** In the space provided online for abstracts, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the research proposal and its relationship to CF. Two different abstracts are required as follows:
   - **Lay Abstract:** This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
   - **Scientific Abstract:** This statement will be used to inform the scientific community.

**Summary of Relevance to CFF mission**

All applications are reviewed and scored not only on scientific merit but also on relevance to CFF’s mission.

> The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

Provide a statement of no more than 2,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a non-scientific audience who may or may not have a background in the subspecialty of the proposed research.

7. **Budget Summary:** Fill in the start date and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2). All Lung Transplantation Awards are awarded for a maximum of two (2) years, up to:
   - **$350,000 per year in direct costs (plus 8% indirect costs) for a Collaborative Project**
   - **$150,000 per year in direct costs (plus 8% indirect costs) for an Independent Project**

**Note:** The Budget Detail template and Budget Justification template downloaded in Section #2 on proposalCENTRAL must be completed and uploaded in Section #10 for each year of funding being requested and for each subcontract (if applicable).

8. **Organization Assurances:** Select the type of assurances that are applicable to the project and provide all required information (i.e. IRB, IACUC, and/or IBC/rDNA approval letter and status at the time of submitting your application). Refer to Section L. ORGANIZATION ASSURANCES & CERTIFICATIONS in these guidelines for details.
9. **Research Plan & Supporting Documents**: In this section, upload the completed templates downloaded in Section #2 above. Fill out the fields describing the attachment, select the attachment type from the pulldown menu, choose the file to be uploaded, and click the “Upload Attachment” button to upload the file. Do this for each attachment.

Below are instructions specific to each template as well as additional information regarding other application components.

A. **RESULTS OF PAST AND CURRENT CFF/CFFT SUPPORT** (template available for download)
   Identify the results of past and current CFF/CFFT support (e.g., subsequent funding from other sources, journal articles, and invited presentations) and the CFF/CFFT award from which they resulted for the past five years. Please note that the following information must be included with each research project identified:
   - CFF/CFFT Award #
   - Principal Investigator (PI)
   - CFF/CFFT Project Title
   - Applicant’s Title on Project
   - Project Start/End Dates
   - Total CFF/CFFT Award Amount
   - Results of Support

B. **BUDGET DETAIL AND BUDGET JUSTIFICATION** (separate templates available for download)
   Fill out the Budget Detail and Budget Justification templates for each and all years of support requested. In the space provided on each page, indicate the year or period as well as start and end dates for the proposed budget period. Up to two (2) years of funding may be requested. In addition, if there are subcontracts, each subcontract requires a separate Budget Detail and Budget Justification for each year. (Be sure the Budget Summary in Section #8 aligns with the Budget Detail).

   Funding up to **$350,000 per year, for two (2) years**, plus eight percent (8%) indirect costs for collaborative projects or up to **$150,000 per year, for two (2) years**, plus eight percent (8%) indirect costs for independent projects.

   - **Budget Detail – Direct Costs**
     - **Personnel** - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **$189,600**; when calculating salary requests, the NIH cap must be adhered to. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.
     - **Consultant Costs** – Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with
patient care if they are not listed under personnel. Under budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs.

**Equipment** – List all items of equipment greater than $5,000 requested and the cost of each. If funds are requested to purchase equipment that is equivalent to items listed under “Facilities Available”, justify the duplication. Justify any item of equipment for which the need may not be obvious.

**Supplies** – Itemize supplies, such as glassware, chemicals, animals, etc., in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

**Travel** - Describe the purpose of any CF-relevant travel. Up to $2,000 per person, per year, may be requested. All travel expenses must comply with the CFF Volunteer/Vendor Expense Reimbursement Policies. Expenses for travel outside the North American continent for domestic applicants, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the Grants and Contracts Office. Registration fees associated with conferences should be listed under “Other Expenses.”

**Other Expenses** - Itemize other expenses by major categories, such as subcontracts, duplication costs, publication costs, conference registration fees, computer charges, etc. Justify all items. Tuition costs are not allowed on this award.

**Subcontracts** – The total cost of each subcontract (directs plus indirects) should be listed under “Other Expenses” and included in the applicant’s direct costs. The applicant institution may request indirects only on the first $25,000 of each subcontract for the entire project period. Detailed budgets for each subcontract must be provided for each year of support. Negotiations of subcontracts are between the applicant institution and the subcontractor.

- **Budget Detail – Indirect Costs**
  Indirect Costs up to eight (8) percent may be requested from CFF. Indirect costs may be requested for all expenses except for the following:
  - Major equipment (items over $5,000 in value)
  - Computer software
  - Software licenses

- **Budget Justification**
  Describe and justify the line items in the Budget Detail. Use major categories, such as Personnel, Consultant Costs, Equipment, etc.

C. **FACILITIES AVAILABLE (template available for download)**
Describe the facilities and equipment available at the applicant’s institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant’s or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.
D. BIOGRAPHICAL SKETCH(ES) OF KEY PERSONNEL (NIH template and example available for download)
CFF defines “key project personnel” as any individual with an advanced degree who will play an instrumental role in the research project. An NIH Biographical Sketch form should be completed for each key project personnel and uploaded as PDF. The maximum length for each biosketch is five (5) pages. Personnel must include a biostatistician with at least 5% effort on the project.

E. OTHER SUPPORT (NIH template and example available for download)
Complete and upload an “Other Support” form, for all key project personnel, beginning with the Principal Investigator. There is no page limitation.

F. PROPOSED RESEARCH PLAN
Include sufficient information to permit effective review. Information should be presented in a clear and concise manner, while being specific and informative.
- Key figures and legends must be included in the Research Plan. If uploaded as Appendices, they will not be reviewed.
- At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom.
- Page limit: Twelve (12) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.

a. Hypothesis and Specific Aims. State concisely and realistically the intent of the proposed research and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.

b. Background and Significance. Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF in particular those listed as areas of special interest to CFF. In addition, for postdoctoral fellowship applications, describe the relationship of the proposed work to your long-term career goals.

c. Preliminary Results. If applicable, provide a detailed discussion of any preliminary results.

d. Experimental Design and Methods. Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations or materials that may be hazardous to personnel or patients and
the precautions to be exercised. Discuss the potential difficulties and limitations of the proposed procedures and alternative strategies for achieving the aims.

*For sample size estimates, please provide all estimates of means, standard deviations, rates or proportions used to calculate each of your sample size or power estimates. Please include in the statistical section whether you will use a one or two-tailed test, the power selected for such a test (if making a sample size calculation), and the reference for your sample size or power calculation. In instances of pilot studies where some of these parameters are unknown, we will accept your best estimates of the unknown parameters if preliminary data are not available, and if your calculation is a preliminary estimate before formal sample size can be calculated for a larger study. Please identify if you are making estimates from data or from personal estimates. This section must document access to adequate numbers of subjects.

e. Literature Cited. References should be numbered in the sequence that they appear in the text and listed at the end of the Research Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

G. COLLABORATIVE PROJECT DESCRIPTION (template available for download, if applicable)
Maximum of two (2) pages. Include a list of collaborators and institutions, and describe the following:
• How the individual applicant fits within the larger collaboration
• The synergy among the groups
• Value added from the collaboration with other applicants to this program
• How the individual applicants will communicate and collaborate (e.g. sharing reagents and data)
• Consultant arrangements and/or collaborations (if any) with other investigators outside the designated collaboration.

H. LETTERS OF SUPPORT FROM COLLABORATORS/CONSULTANTS (if applicable)
Upload each letter individually. Be sure to provide a description distinguishing each letter. Letters must be provided per the following:
• Co-Principal Investigator(s). A signed letter from Co-PIs (if any) must be uploaded with the letters of support.
• Collaborative Projects. Signed letters of support must be provided from all collaborators and should include a brief description of the collaboration, and the value added from the collaboration.
• Consultants/Collaborators. For consultant arrangements with investigators outside the applicant’s or Collaborative Project’s group, the letter should describe the working relationship.
• Collaborators who are furnishing required clinical materials. The letter should include a statement agreeing to their participation and precautions taken to ensure anonymity of patients.

I. APPENDICES (upload applicable materials as PDF documents)
Appendices are restricted to the following areas:
• **Organization Assurances and Certifications**
CFF requires, as applicable, and if available at the time of submission, all necessary Institutional Review Board (IRB) approvals for human subject research, Institutional Animal Care and Use Committee (IACUC) approval for animal research, and Institutional Biosafety Committee (IBC) approval for recombinant DNA research. Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices, or provided to CFF as soon as they are available. Delays in providing these approvals to CFF will affect the release of payments to Awardees. Please note, in the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must be submitted to CFF.

• **Up to three (3) reprints** of the applicant’s work relating to the general area of work in the proposal.

• **Other materials** pertinent to the proposal, not already described (e.g. Registration documentation for Investigator-Initiated Clinical Trials).

**J. VERIFICATION OF APPLICANT INSTITUTION’S TAX STATUS (upload ad PDF documents)**
The Grants and Contracts Office must have a copy of the applicant institution’s current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

• Applicants from for-profit organizations must submit a copy of the applicant institution’s W-9 and IRS Form 147C, or other documentation verifying the organization’s Federal tax status. Awards are not issued prior to having these documents on file with the Grants and Contracts Office.

• Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

**K. INTERNATIONAL INSTITUTION FORM (template available for download, if applicable)**
Applicants whose awardee institution is not a United States based entity must complete the International Institution Form. **Upload a PDF version of the completed and signed form, together with the following documents***:

• A copy of the institution’s most recent Mission Statement.

• A copy of the institution’s Tax Exemption Letter or equivalent, if institution is a nonprofit.

• A brief description of other sources of support, such as official awards, private endowments, and commercial activities, received by the institution.

• A copy of the institution’s Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks, nor are funds used for activities that support terrorism or terrorist organizations.

• For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management.

*Applicants must provide English translations for all non-English documents, including material provided in support of the Research Plan.*

10. **PI Data Sheet: Fill in the required fields, save and exit.**
11. **Validate**: Upon completing your application, click on the “**Validate**” button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click “**Validate**” again.

12. **Print Face Pages**: Follow the prompts on the screen to generate and print a face page. The Face Page will be populated automatically with data entered in the online application (applicant’s name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Co-Principal Investigators, if any, are not expected to sign the Face Page. **Scan and email the signed Face Page to grants@cff.org in conjunction with the application submission on proposalCENTRAL.** No hardcopy is required.

13. **Submit**: Click on the gray button with blue lettering. **Submit** CFF will not receive your application until and unless the “**Submit**” button is clicked.

**Confirmation**: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

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**For technical support with the online application:**
proposalCENTRAL at pcsupport@altum.com or 800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

**For program/content information:**
CFF Grants and Contracts Office at grants@cff.org or 301-841-2614
VIII. ELECTRONIC APPLICATION CHECKLIST

LOI Submission Deadline: Tuesday, July 10, 2018 at 5:00 PM (EST)
Full Application Deadline: Monday, September 24, 2018 at 5:00 PM (EST)

Application must be submitted online at proposalCENTRAL: https://proposalcentral.altum.com/

A PDF copy of the signed Face Page (Full Application Only) must be emailed to CFF (grants@cff.org) by the same deadline. The complete application must be submitted online, and no other documents will be reviewed.

LETTER OF INTENT
☐ Signed Letter of Intent Cover Sheet - (upload)
☐ Budget Summary – (complete online)
☐ Letter of Intent Project Description – (upload)
☐ Biographical Sketch(es) of Key Personnel - (upload)

FULL APPLICATION
Face Page (sign and email to grants@cff.org), which includes:
☐ Signatures
   □ Principal Investigator (Co-PI’s are not required to sign)
   □ The Official authorized to sign on behalf of the Applicant Institution
☐ Applicant/PI information - (online)
☐ Complete Institution and PI Contact information, including correct mailing address - (online)
☐ Organization Assurances (check those that apply online)
   □ Human Subjects Certification - Minimal patient risk only
   □ Recombinant DNA Biosafety information
   □ Research Involving Animals information

Research Plan & Supporting Documents:
☐ Results of Past and Current CFF/CFFT Support – (upload)
☐ Budget Detail individually for each year requested (including subcontracts) – (upload)
☐ Budget Justification individually for each year requested (including subcontracts) – (upload)
☐ NIH Biographical Sketch(es) of Key Personnel – (upload)
☐ Other Support for all Key Personnel – (upload)
☐ Research Plan – (upload)
   □ Hypothesis and Specific Aims
   □ Background and Significance
   □ Preliminary Results
   □ Experimental Design and Methods
   □ Literature Cited (not included in page limit)
☐ Collaborative Project Description – (upload)
☐ Letters of Support from Collaborators/Consultants – (upload, as applicable)
   □ Co-Principal Investigator(s)
☐ Collaborative Projects
☐ Consultants/Collaborators
☐ Collaborators who are furnishing required clinical materials

☐ Appendices – (upload, as applicable)
  ☐ Organization Assurances and Certifications
  ☐ Up to three (3) reprints of the applicant’s work relating to the general area of work in the proposal.
  ☐ Other materials pertinent to the proposal, not already described (e.g. Registration documentation for Investigator-Initiated Clinical Trials).

☐ Verification of Applicant Institution’s Tax Status - (upload)
  ☐ W-9 (US applicants) or W-8BEN-E (non-US applicants)
  ☐ 501(c)3, IRS Form 147C or equivalent tax status letter

☐ International Institution Form (non-US based entities only) - (upload, if applicable)
  ☐ Institution’s most recent Mission Statement
  ☐ Institution’s Tax Exemption Letter, if institution is not-for-profit
  ☐ Description of other sources of support
  ☐ Institution’s Standard Operating Procedure(s) or relevant policy to ensure that funds provided are neither distributed to terrorists or their support networks nor used for activities that support terrorism or terrorist organizations
  ☐ For-profit institutions must submit a complete list of key employees, members of the governing board, and/or other senior management